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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,166	12/08/2000	Richard W. Compans	96-99	2363
23713	7590	04/01/2004	EXAMINER	
GREENLEE WINNER AND SULLIVAN P C 5370 MANHATTAN CIRCLE SUITE 201 BOULDER, CO 80303			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/733,166

Applicant(s)

COMPANS ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 62,64,65 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 62,64,65 and 67-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

**Due to the typographic error made by the previous Office Action, the previous Office Action is vacated. A new Office Action is issued as follow:**

#### **Reopen**

This is reopen prosecution because after reconsidering the claimed invention, new grounds of rejections are established on the record. Office apologizes any inconveniency that brought by this reopen practice.

#### ***Response to Amendment***

This is a response to the amendment, paper No. 26, filed 12/21/03. Claims 62, 64-65 and 67-70 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 62, 64-65 and 67-68 are still are rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, because the specification, while being enabling for using a formalin inactivated influenza virus P8/5 to induce a serum immune response in a CD4 deficient mouse model, does not reasonably provide enablement for using any or all inactivated of attenuated virus to induce a serum immune response in a CD4 deficient animal and human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
2. Applicants traverse the rejection and submit that the claimed invention is based on the inventors' actual data that formalin inactivated intact influenza virus induce antibody production in mice lacking functional CD4+ T cells. And applicants argue that the examiner does not provide an objective scientific reason why a skilled artisan would not expect that any attenuated or inactivated virus can not induce an immune response in a CD4+ cell deficient subject as was demonstrated in the specification using influenza virus as example.

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3. Applicants' argument has been respectfully considered; however, it is not found persuasive because the state of art indicate that vaccination of immune compromised patients, such as HIV infection patients, is very unpredictable. Sometime, it increases the plasma virus burden as evidenced by Brichacek et al. (J. Inf. Dis. 1996, Vol. 174, pp. 1191-1199). Sometime, it does not have any response too. For example, Brichthe et al. reported that vaccination of HIV-1 positive patients with subunit Pneumococcal and influenza vaccine increase the plasma HIV viral load (See Figs. 1-4 on page 1194-1198).

4. Moreover, the scope of the claims read on any or all viruses, and each viruses as recited in claim 69, for example, exhibits different molecular structure and contains different molecular component. Whereas, the specification only provide the example of using formalin inactivated P8/5 influenza virus in CD4 deficient mice. There is not enough evidence to support the broadly claimed invention, especially, it read on a method for treating human being. Therefore, the rejection is maintained.

## 5. New Ground Rejections:

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 62, 67, 68, 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. (J. Acquired Immunol Deficiency Syndromes and Human Retroviruses, 1996, Vol. 11, pp. 351-364).

3. Levine et al. disclose an method of inducing an active immune response of HIV-1 infected patients having a CD4 using a  $\beta$ -propiolactone inactivated HIV-1 virus having a gp12-depletion in complete Freund's adjuvant (IFA). After 6 year treatment, nine patients showed fourfold or greater increase in anti-p24 antibodies titers (See entire document, especially, section of Preparation and Use of the Immunogen on page 352, line 1-12, Table 1 on page 354 and lines

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1-12 on section of Humoral Immune Response on page 358). Therefore, the claimed invention is anticipated by the cited reference.

4. Claim 70 is rejected under 35 U.S.C. 102(b) as being anticipated by Jackson et al. (Pediatr. Infect. Dis. J. 1997, Vol. 16, No. 2, pp. 200-204).

5. Jackson et al. teach a method for immunizing the HIV-infected children, who have the CD4 deficiency, with influenza vaccine comprising the inactivated influenza virus. They found that all children response to the influenza vaccine with more than 2-fold to 4 folds increase of their influenza antibody titers (See entire document, especially, the abstract). Therefore, the claimed invention is anticipated by the cited reference.

### ***Conclusion***

No claims area allowed.

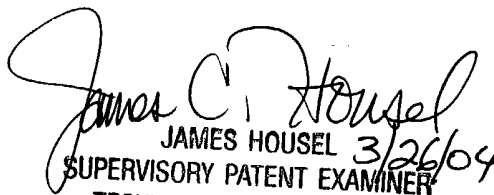
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0906. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

03/05/2004

  
JAMES HOUSEL 3/26/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600